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13. ABSTRACT (Maximum 200 Words) <p>High quality mammographic images enhance the radiologist's ability to interpret mammograms. Image quality is dependent upon adequate visualization and inclusion of tissue, adequate exposure, contrast and resolution; and proper compression. Meeting these criteria is essential to detection of cancer, since 73% of cancers are located in the peripheral or retroglandular fat. Pendant mammography, is a procedure whereby the patient leans forward 15 to 25 degrees during mammography, pulling the breast away from the body, and thereby increasing the amount of retroglandular breast tissue evident on a mammogram. We propose to test the benefits of pendent mammography by imaging 250 women by acquiring both conventional and pendent mammograms. We will then perform a quantitative analysis of the mammograms, to determine the effect of leaning on the amount of breast tissue imaged, the compression obtained, and the dose to the breast.</p> <p>Fifty-one patients have enrolled in this study as of September 30, 2004. Reader studies of resultant images have begun. We are awaiting approval from the USAMRMC to establish a subaward with Dr. Andrew Maidment at the University of Pennsylvania to digitize and begin physical analysis of the images.</p>				
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Introduction

High quality mammographic images enhance the radiologist's ability to interpret mammograms. Image quality is dependent upon adequate visualization and inclusion of tissue, adequate exposure, contrast and resolution; and proper compression. Meeting these criteria is essential to detection of cancer, since 73% of cancers are located in the peripheral or retroglandular fat. Pendant mammography, is a procedure whereby the patient leans forward 15 to 25 degrees during mammography. The thought is that gravity aids in pulling the breast away from the body, thereby increasing the amount of retroglandular breast tissue evident on a mammogram. Thus, pendant mammography should simplify positioning making adherence to these criteria simpler and more frequent, as well as allowing better and less painful compression. There have been no published studies to quantify the benefits of pendant mammography. We have anecdotal evidence that pendant mammography provides superior images of the breast by including more tissue near the chest wall. In routine clinical practice at Thomas Jefferson University Hospital (TJUH) we feel that 0.5 to 1.0 cm of additional breast tissue is seen when pendant. It is also more common to see the posterior margins of the glandular tissue when pendant. We propose to test the benefits of pendant mammography by imaging 250 women by acquiring both conventional and pendant mammograms. We will perform a quantitative analysis of the mammograms, to determine the effect of leaning on the amount of breast tissue imaged, the compression obtained, and the dose to the breast.

The work to date is reviewed in this annual report.

Body

Summary of Work Items

The following work items have been defined.

- 1) Develop a detailed clinical trial protocol, applicable forms, etc.
- 2) Enroll and image 250 women with both pendant and erect mammography
- 3) Perform a reader study of the resultant images
- 4) Perform a physical analysis of the resultant images
- 5) Perform a statistical analysis
- 6) Report results.

To date, we have completed item (1), and we have begun enrollment of patients [item (2)] and performance of the reader study of the resultant images [item (3)].

Discussion and Summary of Scientific Results

Enrollment of patients and the reader studies have begun. IRB approval was sought from the University of Pennsylvania to enable Dr. Andrew Maidment access to the resultant images for digitization and physical analysis. Although the University of Pennsylvania IRB approved the study on March 30, 2004, an amendment had to be submitted to Thomas Jefferson University's IRB to formally add Dr. Maidment as a co-investigator and approve release of the images to Dr. Maidment. The amendment was approved on May 26, 2004.

Upon reviewing the grant agreement, it was determined that we could not enter into a subcontract for Dr. Maidment to perform the digitization and physical analysis of the images without prior approval from the Department of the Army. A request for prior approval was sent to the USAMRMC on September 10, 2004. The letter also requested a no cost extension to allow us to complete enrollment, as well as enable us to establish a subaward with Dr. Maidment to perform the digitization and physical analysis of the images.

We are awaiting a response from the USAMRMC to proceed with the establishment of the subaward and study analysis.

Key Research Accomplishments

Fifty-one patients were enrolled as of September 30, 2004. The first patient was enrolled on July 30, 2003. Ages of the subjects ranged from 30 to 88, and are summarized below. The population consists of 36 Caucasian females, 12 African-American females, 2 Asian females, and 1 Hispanic female.

<u>AGE</u>	<u># subjects</u>
30 – 39	3
40 – 49	17
50 – 59	17
60 – 69	11
70 – 79	2
80 – 89	1

Reportable Outcomes

None

Conclusions

In conclusion, we propose to evaluate the benefits of pendant mammography. To date, the patient enrollment and the blinded reader studies have begun. Analysis of the images is anticipated once the USAMRMC approves the subaward to Dr. Maidment to digitize and perform physical analysis of the images, as well as providing approval for the no cost extension.